IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litigation	Master Docket No. 20-1076-CFC
This Document Relates to:	
All Actions	

MEMORANDUM ORDER

Pending before me is Plaintiffs' *Daubert* Motion No. 1 to Exclude the Opinions of Handa's Expert Mr. Walter Lunsmann. D.I. 641.

I.

These class actions arise out of a 2011 agreement to settle a patent lawsuit relating to extended-release quetiapine fumarate, an anti-psychotic drug sold by Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively, AstraZeneca) under the brand-name Seroquel XR® (Seroquel). AstraZeneca had alleged in the underlying lawsuit that generic versions of Seroquel made by Defendant Handa Pharmaceuticals LLC and other generic manufacturers were covered by one of AstraZeneca's patents and that abbreviated new drug applications (ANDAs) filed by Handa and the other manufacturers with the Food and Drug Administration (FDA) to market their respective generic versions of

Seroquel constituted patent infringement under the Hatch-Waxman Act. *See* 35 U.S.C. § 271(e)(2)(A) (making the submission of an ANDA "an act of infringement . . . for a [generic] drug claimed in a patent or the use of which is claimed in a patent" for the brand drug).

Although the patent's expiration date was May 28, 2017, AstraZeneca was entitled to an additional six-month period of the patent's exclusivity under 21 U.S.C. § 355 because of AstraZeneca's participation in pediatric studies of Seroquel. D.I. 627 ¶ 4; D.I. 718 ¶ 4. Thus, as long as the patent remained valid, it effectively precluded a manufacturer from marketing before November 28, 2017 a generic version of Seroquel that infringed the patent unless that manufacturer had a license from AstraZeneca.

As part of an agreement to settle its case against Handa, AstraZeneca paid Handa $4 million in cash, licensed the asserted patent exclusively to Handa as of November 2016 (i.e., a year before the patent's pediatric exclusivity period ended), and agreed not to launch its own generic version of Seroquel during the 180-day period in which only Handa and AstraZeneca had FDA approval to lawfully market a generic version of Seroquel—thus ensuring that the only generic versions of Seroquel on the market during that period would be sold by Handa, which enjoyed a 180-day period of exclusivity as the generic first filer. D.I. 718 ¶ 59; D.I. 627 ¶¶ 16–17; *see also FTC v. Actavis, Inc.*, 570 U.S. 136, 143–44 (2013)

(explaining that the first generic manufacturer to file with the FDA an ANDA to market a generic drug "will enjoy a period of 180 days of exclusivity" and that "[d]uring that period of exclusivity[,] no other generic can compete with the brand-name drug"); *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 393 (3d Cir. 2015) (holding that "[t]he relevant statute permits the brand to produce an 'authorized generic' during the [first generic filer's] exclusivity period") (citations omitted).

Plaintiffs allege that these settlement terms constituted an unlawful "reverse payment"—i.e., a payment made *by the plaintiff* (AstraZeneca) *to the defendant* (Handa) to settle claims *brought by the plaintiff*—that delayed and suppressed competition among sellers of generic versions of Seroquel in violation of the Sherman Act, as interpreted in *Actavis*. Plaintiffs allege that as a result of this delay and suppressed competition, they paid more than they should have for branded and/or generic versions of Seroquel. D.I. 135 ¶ 25. And they say that the settlement agreement's reverse payment caused them this antitrust injury because, but for that payment, AstraZeneca and Handa would have entered into an alternative settlement agreement that would have allowed Handa to launch generic versions of Seroquel in July 2015. *See* D.I. 635-1 at 22.

One of the limitations in the claims of the patent asserted by AstraZeneca in the underlying lawsuit was "a gelling agent." Handa told AstraZeneca before the

lawsuit that its generic versions of Seroquel did not literally infringe the patent because they did not contain a gelling agent. D.I. 653-1 at 14. Handa asserted this same noninfringement defense in the underlying suit. D.I. 653-1 at 71–74.

Handa intends to call at trial Walter Lunsmann to testify as an expert and specifically to testify that in his opinion colloidal silicon dioxide (CSD), which was an ingredient of Handa's generic versions of Seroquel, "can be considered a 'gelling agent' as that phrase was construed in the underlying infringement case" between Handa and AstraZeneca. D.I. 711 at 10. Handa says that this expert testimony "will help the trier of fact understand why [Handa] would settle with AstraZeneca instead of proceeding to a trial that it could lose[.]" D.I. 711 at 3.

Plaintiffs have moved pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) to preclude Mr. Lunsmann from offering this opinion at trial. D.I. 641.

II.

Federal Rule of Evidence 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;

> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. In *Daubert,* the Supreme Court held that district courts must act as gatekeepers to ensure that proffered expert scientific testimony meets the requirements of Rule 702. *See* 509 U.S. at 589. And in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), the Court held that "this basic gatekeeping obligation" "applies to all expert testimony," and not just "scientific" testimony. *Id.* at 147.

At issue here is Rule 702's requirement that the expert's knowledge "help the trier of fact to understand the evidence or to determine a fact in issue." The Third Circuit has called this the "fit" requirement. *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003); *see also Daubert*, 509 U.S at 591 (noting that Rule 702's helpfulness requirement was "aptly described by Judge Becker as one of 'fit'"). As the Court explained in *Schneider*, "Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." 320 F.3d at 404.

III.

Plaintiffs argue that neither AstraZeneca nor its experts in the underlying patent suit were asserting that CSD was a "gelling agent" at the time AstraZeneca

and Handa settled the case and that therefore Mr. Lunsmann's opinion does not fit the facts of this case and should be excluded under Rule 702 and *Daubert*. According to Plaintiffs, "[b]y the time of the challenged reverse payment agreement, the ***only*** remaining infringement question in the litigation between Handa and AstraZeneca was whether the *hydrogenated vegetable oil* ('HVO') [(i.e., not the CSD)] in Handa's ANDA Product constituted a gelling agent," D.I. 652 at 3 (emphasis in the original), and that therefore Mr. Lunsmann's opinion has no relevance to the likely outcome of the underlying patent case.

Handa counters that "Mr. Lunsmann's testimony 'fits' this case for the same reason Plaintiffs intend to offer testimony about how a reasonable patent litigator would advise Handa prior to trial – a belief about the likelihood of success at trial is directly relevant to the decision to enter into a settlement." D.I. 711 at 4. According to Handa, "AstraZeneca's litigation position kept alive the prospect that other excipients in the Handa ANDA Product, like CSD, were a gelling agent when used in combination with the hydrogenated vegetable oil." D.I. 711 at 7. At oral argument, Handa's counsel repeated this claim, insisting that AstraZeneca "never fully abandoned that [CSD] could be either alone or in conjunction with HVO, part of the gelling agent" and thus the presence of CSD in Handa's product was "still an issue in the underlying case." 2.6.25 Tr. 230:6–9 (docketed as D.I. 825).

The record in the underlying case flatly contradicts Handa's position. The record makes abundantly clear that as the parties readied themselves for trial, the sole question with respect to the gelling agent limitation was whether the HVO in Handa's accused product met the limitation. In its "Outline of Trial Proofs," AstraZeneca stated that the "***only*** infringement issue[] to be tried" was whether the HVO in Handa's product amounted to a "gelling agent[]." D.I. 653-1 at 240 (emphasis added). And in its "Intended Proofs," Handa similarly stated that its "evidence of non-infringement will be directed to the ***single issue*** of establishing that the Hydrogenated Vegetable Oil (HVO) in Handa's product is not a 'gelling agent' as required by the asserted claims." D.I. 653-1 at 254 (emphasis added). The reports of AstraZeneca's experts in the underlying litigation, Drs. Prud'homme and Davies, also confirm that AstraZeneca was focused solely on the theory that HVO infringed the asserted patent's "gelling agent" limitation. *See* D.I. 653-1 at 112 ("[I]t is my opinion that the HVO in Handa's Proposed ANDA Products forms a gel to provide sustained release."); D.I. 653-1 at 101 ("These images show a network structure formed by the HVO where water can enter into the tablet, and where quetiapine is dissolved and diffuses in an aqueous phase out of the tablet."). Handa's own experts' reports were similarly focused on HVO. *See, e.g.*, D.I. 653-1 at 119 ("Accordingly, these results suggest that HVO does not

form a gel when in contact with water."); D.I. 653-1 at 134 ("The HVO in Handa's product is not a 'gelling agent' as that term is used in claim 1.").

Because the undisputed record evidence establishes that the question of whether CSD was a gelling agent was not an issue in the underlying patent case at the time AstraZeneca and Handa reached a settlement agreement, Mr. Lunsmann's opinion that CSD could constitute a gelling agent has no relevance to the likely outcome of the underlying patent case or the reasonableness of the challenged settlement agreement. Accordingly, Mr. Lunsmann's opinion fails to satisfy Rule 702's fit requirement with respect to those issues, and I will grant Plaintiffs' motion to the extent it seeks to bar Handa from adducing Mr. Lunsmann's opinion at trial with respect to those issues.

Handa, however, also argues in its opposition brief that "whether CSD can be considered a 'gelling agent' is relevant to Handa's subjective belief about the strength of its position in the underlying litigation and the legitimate justifications for its decision to settle." D.I. 711 at 10. Plaintiffs say that "Handa blocked discovery o[f] both its subjective beliefs and those of [its CEO,] Dr. Liu at the time of settlement, and therefore [it] should not be permitted to offer Mr. Lunsmann's testimony to bolster those alleged—but withheld—beliefs." D.I. 777 at 3 (emphasis removed). From my preliminary review of the discovery materials and my recollection of a discovery conference during which I warned Handa that it

could not "take advantage of" inconsistent privilege claims and use "privilege to [its] advantage in a way that prejudices [Plaintiffs] unfairly," 7.13.23 Tr. 149:13–14, 146:9–10 (docketed as D.I. 455), I am sympathetic to Plaintiffs' position. But Plaintiffs have not cited, let alone discussed, any case law or other legal authority to support their position, and it is undisputed that Handa allowed some (albeit very limited) discovery of the subjective beliefs of Handa's CEO about the underlying patent case. Accordingly, I think the prudent course of action is to defer ruling on whether Mr. Lunsmann's opinion would be admissible at trial with respect to the reasonableness of Handa and Dr. Liu's subjective beliefs until I first determine whether Handa will be permitted to adduce evidence at trial about those beliefs.

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NOW THEREFORE, at Wilmington on this Twentieth day of March in 2025, it is HEREBY ORDERED that Plaintiffs' *Daubert* Motion No. 1 to Exclude the Opinions of Handa's Expert Mr. Walter Lunsmann (D.I. 641) is GRANTED IN PART AND DEFERRED IN PART.

CHIEF JUDGE